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DIVISION OF PROFESSIONAL REGULATION

PUBLIC MEETING NOTICE:	BOARD OF PHARMACY
DATE AND TIME:	Wednesday, April 20, 2011 at 9:30 a.m.
PLACE:	Conference Room A, Cannon Building 861 Silver Lake Blvd., Dover, DE 19904
APPROVED:	

MEMBERS PRESENT

Sebastian Hamilton, R.Ph, Professional Member, President
Howard Simon, R.Ph, Professional Member, Vice President
Sandra Robinson, R.Ph, Professional Member
Joli Martini, R.Ph, Professional Member
Geoffrey N. Christ, Esq., R.Ph, Professional Member
Don Holst, R.Ph, Professional Member
Matt Maher, Public Member
Jay Galloway, Public Member

MEMBERS ABSENT

David Bonar, Public Member

DIVISION STAFF/DEPUTY ATTORNEY GENERAL

David W. Dryden, R.Ph., J.D., Executive Secretary
Allison Reardon, Deputy Attorney General

ALSO PRESENT

Suzanne Raab-Long
Trent Beach
Jeanne Chiquione
Leena Amin
Ravikiran Tatikonda
Brian Connolly
Veronica Dada
Dennis Yoney
Chad Morris
Cheryl Heiks
Tiffany Sorey

CALL TO ORDER

Mr. Hamilton called the meeting to order at 9:35 a.m.

REVIEW OF MINUTES

The February 16, 2011 minutes will be reviewed and approved at the next meeting.

PRESIDENT'S REPORT

Mr. Hamilton stated that on March 25, 2011 he and Mr. Holt attended a meeting concerning the national Drug TakeBack program. The next schedule date to take back any unwanted or unused medication April 30, 2011.

Mr. Hamilton welcomed the Board's new public member Matt Maher.

UNFINISHED BUSINESS

Legitimate Medical Purpose – Internet Pharmacy Proposal

No report

Drug Disposal

Mr. Dryden reported that the national drug disposal event is scheduled on April 30, 2011 from 10 am to 2 p.m. The sites have been determined as of March 31, 2011 and are available at the DEA Diversion web site or at the Division's web site of www.dpr.delaware.gov.

Schedule Disciplinary Hearing

A disciplinary hearing will be scheduled for Michael Tulish at the June 15, 2011 meeting.

Complaint Status

Mr. Hamilton and Mr. Dryden reported that the complaints had been reviewed as the Board had requested. No further hearings would be necessary. A motion was made by Ms. Robinson, seconded by Mr. Christ close cases 13-37-08, 13-06-09, 13-20-09, 13-03-09, 13-39-08, 13-36-08, 13-31-08, 13-29-08, 13-28-08, 13-13-09, 13-12-09, and 13-02-10. The motion was unanimously carried.

NEW BUSINESS

Pharmacist-In-Charge (PIC) and Consultant Interviews

Mr. Simon conducted the PIC interviews for Leena Amin, Ravikiran Tatikonda, Brian Connolly, and Veronica Dada

Pharmacist Consultant Interviews

No consultant interviews were necessary.

Pharmacist Licensure Ratifications

A motion was made by Mr. Simon seconded by Mr. Holst, to ratify the applications of Thomas Wolters, Alethia Medley, Robert Puni, Gunjan Shah, Julianne Martine, Kyung Hee Lee, Deborah Jungling, Andrew Krytzer, Brian Connolly, and Mahendra Chaudhan. The motion unanimously carried.

Ratification of Facility Applications

A motion was made by Mr. Christ seconded by Mr. Simon, to ratify the licensure of the non-resident pharmacies BioRx, GreenValley Drugs Home Health, Brockie Pharmatech, Cystic Fibrosis Services, Inc, Elwyn Specialty Care, Hometech Therapies, Inc, Acro specialty Pharmacy, LLC, Veterinary Mart, Corp, and Homechoice Partners, Inc. The motion was unanimously carried.

A motion was made by Ms Robinson seconded by Ms. Marini, to ratify the licensure of the medical gas dispensers Pacific Pulmonary Services and Med-Equip, Inc. The motion was unanimously carried.

A motion was made by Mr. Simon seconded by Mr. Christ, to ratify the retail pharmacy licensures of Rodney Village Pharmacy, LLC., Grubbs Pharmacy, CCHS Mail Order Pharmacy, People's Pharmacy, and Georgetown Pharmacy & Medical Supply. The motion was unanimously carried.

A motion was made by Ms. Martini. seconded by Mr. Simon, to ratify the wholesale distributor licensures of Excel Inc., FMC Distributor Inc., Priority Healthcare Distributor, Inc., Edwards Lifesciences Technology, Merz Aesthetics, Inc., Masters Pharmaceutical, Inc., Piramal Critical Care, Inc., National Hospital Specialty, Owens & Miner Distribution Inc., J. Knipper & Company, Inc., Amgen USA, Inc., Amerisource Bergen Drug Corp., US Oncology Specialty , LP, Premium RX National, LLC, and Centurion Medical Products, Corp. The motion was unanimously carried.

Patient Own Medication

Mr. Dryden provided correspondence from Samuel Roberts, PIC Beebe Hospital. Mr. Roberts has concerns regarding patient's bringing there own medications into the hospital for administration. Patients who come to the hospital on an outpatient basis may stay at the hospital for 2-3 days. During this time they wish to take there own medications dispensed to them by their local community pharmacy. Beebe would obtain the medication from the patient, identify the medication and then send the medication to the floor for future administration. Mr. Roberts is concerned with liability, stability and identification of the medication. Similarly, Mr. Dryden stated that he had spoken to Al Helmeczi, CMC and Robert Thornton, Wilmington Hospital regarding their hospital policies. They only allow the same procedure for medications identified with a specific need and those medications not available from their pharmacies. Dr. Beach was available for discussion and stated the same information. After review the Board determined that the Regulation 9.2.1.10 provided the hospitals with the ability to make and utilize a policy for drugs brought in by patients. No further Regulation is needed at this time.

The Board requested that Mr. Roberts be contacted for attendance at a future Board meeting for further discussion on this issue.

A motion was made by Ms Robinson seconded by Mr. Christ, to amend the agenda and allow Mr. Collins to speak. The motion was unanimously carried.

Mr. Collins introduced Roger Akin, Esq. Mr. Akin will be providing panel hearings for the Division which will make the hearing procedures more efficient. Mr. Akins reviewed his

procedures and stated that these policies would be utilized to address issues such as those faced by the Board in the area of continuing education.

A motion was made by Ms Robinson seconded by Mr. Simon, to return to the agenda. The motion was unanimously carried.

CPR Review for Immunization Qualifications

Mr. Dryden stated that as per Regulation 14.1.1.2 a current cardio-pulmonary resuscitation (CPR) certificate acceptable to the Board was required by pharmacists who wished to administer injectable medications, biologicals, and adult immunizations. Mr. Dryden stated that the American Health & Safety Institute had provided information for their CPR acceptance. After review of the information provided a motion was made by Mr. Christ seconded by Ms. Robinson, to accept the admission as CPR qualified. The motion was unanimously carried.

Discussion of Recent Superior Court Decision

Ms. Reardon reviewed the recent Superior Court decision regarding the administrative record.

15 Minute Prescription Issue

The 15 minute prescription issue now being advertized by Rite Aid Corporation was reviewed by the Board. Mr. Dryden provided a handout from Rite Aid's Mike Podgurski. After discussion, the Board requested Mr. Dryden send a letter to Rite Aid voicing their concerns and reiterating the fact that personnel would not be disciplined for going beyond the 15 minutes allotted. The letter would be reviewed by Ms. Reardon prior to the mailing.

Some Board members shared concerns over the impression this program gives the public about the profession of pharmacy and the impact to public safety as trying to meet this expectation could lead to more dispensing errors by the pharmacist.

The Board also recommended that Rite Aid management send a letter to its pharmacist staff, and share a copy with the Board, reiterating the comments presented at the meeting from the Rite Aid representation present, that the program will not be used to penalize the pharmacist and the number of \$5 gift cards handed out would not be tracked to measure the pharmacist's performance.

Pharmacy Interview Issue

Mr. Dryden provided a handout of Regulation 3.7 which requires that "applicants for permit to operate a pharmacy in the State of Delaware appear before the Board for an interview. The owner or authorized official must be present in addition to the pharmacist-in-charge." Mr. Dryden first stated and the Board again agreed that he and his staff would process and review the applications, inspect and then license the facilities if the applicants met all of the requirements. The Board would then ratify the license at their next regularly scheduled meeting. The Board agreed. Mr. Dryden then stated that the above Regulation was not being followed because of the Board decision. He recommended the striking of this part of Regulation 3.7. A motion was made by Mr. Christ seconded by Ms. Robinson, to accept the above sentences of Regulation 3.7. The motion was unanimously carried.

Committee Reports

Joint Practice Committee – Don Holst and Howard Simon

Mr. Holst submitted a report, which showed that one APN has received their prescriptive authority.

Physician's Assistant Report – Sebastian Hamilton, R.Ph:

The Board reviewed the report, which stated that the Council met on April 5, 2011 and approved six new applications for licensure, forty applications for control and nine controls for prescriptive authority.

Newsletter – Sandy Robinson, R. Ph., David Dryden, R.Ph., J.D, and Joli Martini, R. Ph.:

Mr. Dryden reported the newsletter had been drafted, sent to NABP and was ready for publication.

Legislative – Sandy Robinson, R.Ph, Howard Simon, R.Ph, Sebastian Hamilton, R.Ph, Don Holst, R.Ph, Geoffrey Christ, R.Ph., Esq., and David Dryden, R.Ph., J.D.:

Mr. Dryden provided a handout of a Pharma amendment to House Bill 235. Ms. Robinson will provide this amendment to Representative Carson

Continuing Education – Sandy Robinson, R. Ph., Geoffrey Christ, R.Ph., Esq., and Joli Martini, R. Ph.:

Mr. Dryden stated that NABP was launching the CPE Monitoring Program. This program was a combined effort of ACPE and NABP to monitor ACPE credits for pharmacists.

Consumer Affairs – Jay Galloway, Matt Maher, and David Bonar: No report.

Professional Liaison – Sandra Robinson, R.Ph. and Joli Martini, R.Ph:

Ms. Robinson informed the Board that on April 20, 2011 the Delaware Society of Hospital Pharmacists will hold their annual Spring Awards banquet and will be offering cpe.

Next Delaware Pharmacist Society Board meeting will be held on April 26, 2011.

MPJE Study Committee – Don Holst, R.Ph, Sebastian Hamilton, R.Ph, and David Dryden:

Mr. Dryden reported that Ms. Kluger, Mr. Kaminski and he had drafted exam questions for the MPJE. He had also spoken to NABP representatives and had voiced Board concerns with "select all that are right" and not using "all of the above" questions. NABP assured Mr. Dryden that we could continue not to use the select all questions and that all of the above type questions would continue to be available on our exam.

Controlled Substance Liaisons – Geoffrey Christ, Howard Simon, and David Dryden:

Mr. Christ reported that a tamper proof meeting was scheduled for May 3, 2011. Mr. Simon stated that proposed controlled substance regulation amendments would be proceeding to hearing in May. The Board requested Mr. Dryden forward the proposed draft to them for their review.

Substantially Related Crimes Committee - Geoffrey Christ, Howard Simon, Patricia Davis Oliva, and Dave Dryden:

No report

Board Correspondence

Mr. Dryden reported he had received correspondence from Neal Benjamin, MC Ltc.. Mr. Benjamin stated he wanted to “reorganize medication” in his pharmacy then utilize this procedure in Delaware as a provider to nursing homes. Mr. Dryden stated that on January 26, 2011 he had sent a return letter to Mr. Benjamin requesting more information regarding his

procedures. To date there has been no return response. Mr. Dryden provided the Board a handout of current re-dispensing, re-packaging and the FDA Customized patient medication packaging standards. Mr. Dryden was concerned that Mr. Benjamin's procedures are in conflict with current laws. Mr. Dryden lastly informed the Board that he had reported this issue to the DEA since this Pennsylvania licensee/registrant also insinuated that he was re-dispensing controlled substances.

Correspondence was received from Walgreens regarding the drop off of medication to sites other than the patient's residence. Mr. Dryden stated that as long as the patient agreed with the drop off site, there was no violation of Delaware drug laws.

Executive Secretary and Inspection Report-David Dryden and Alicia Klugar

Mr. Dryden reported that as requested by the Board, he had contacted the New Jersey Board of Pharmacy and had explained the licensure process in reference to Mr. Ilodigwe.

Mr. Dryden stated that he had been contacted by DPS to provide a Board of Pharmacy/Controlled Substance report to their membership at the DPS annual convention. Mr. Dryden had contacted NABP to assure that there would be no conflict with his speaking at the convention in lieu of his association with MPJE review.

Mr. Dryden presented the Board with a copy of Medication Error Delaware Board of Pharmacy Guidelines, which has been updated at the Board's request, to address a situation of multiple errors and the escalation of disciplines accordingly.

Mr. Dryden reported that President Hamilton and he had met with Pharma regarding electronic prescribing issues.

Mr. Dryden and Ms. Davis-Oliva will be meeting with the Department of Homeland Security and Safety to discuss the amendments to House Bill 235.

Mr. Dryden provided a handout of practitioner requirements that were drafted by the office and would be provided to practitioners during the renewal process.

Ms. Kluger reported that during last 2 months Mr. Dryden and she had completed the following inspections and activities: 4 nursing homes, 8 retail pharmacies, 4 controlled substances audits, 1 researcher, 2 manufacturers, 1 gas provider, 4 pharmacy opening and 6 pre-opening inspections, 3 pharmacy remodels, 3 drop-ins and follow-up and 4 clinics.

Our office was also notified about closure of the Pathmark Pharmacy #540 at 700 Plaza Drive Newark De as of March 18th, 2011

Inspections were conducted in conjunction with FDA; 3 days inspection of the manufacturer in Frankford Delaware, and with the DEA investigator; the inspection of Suboxone treatment center and the practitioner involved in addiction treatment. There are more scheduled openings of this type of facilities in the future in each of the counties in Delaware. Concerns with the inappropriate prescribing and dispensing by the practitioners were referred to the DEA. Department of Professional Regulation included a summary of the requirements that

practitioners must comply with when storing, dispensing and prescribing controlled medications in their renewal application occurring at present time.

The pharmacy providers for nursing home facilities are complying with the DEA requirements of obtaining prescriptions prior to the removal of controlled medications from the emergency supplies by nursing staff. Facilities are making an effort to provide needed medications to the patients and at the same time to comply with the laws. Hospital pharmacy directors were asked to help with this issue by encouraging discharging physicians to write prescriptions for the patients going back to the nursing homes post hospital visits.

Our office had received a request to investigate an issue with oxygen tanks that are being filled by the nursing homes staff to multiple residents utilizing Home Fill Ambulatory Oxygen Package, which is indicated for home use only. This was referred to FDA for further investigation.

Due to the increase in vaccination program, extending to vaccines like Zostavax, that require specific storage condition in addition to the testing in the pharmacies for lipid panels, A1C, etc, Mrs. Kluger will be requesting policies and procedures from the pharmacies conducting such activities to make sure that they comply with USP/NF, OSHA and FDA standards.

Other Business before the Board

None.

Public Comments

None.

Next Scheduled Meeting

The next meeting is scheduled for May 18, 2011.

Adjournment

A motion was made by Mr. Simon seconded by Ms. Robinson, to adjourn the meeting. The motion unanimously carried. The meeting was adjourned at 11:45 a.m.

Respectfully submitted,

Judy Letterman
Administrative Specialist III